

June 20, 2025

VIA EMAIL and ECF

Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street
15th Floor
Newark, New Jersey 07102

**Re: United States ex rel. Silbersher v. Janssen Biotech Inc., et al.,
Civil Action No. 19-12107 (MEF-SDA)**

Dear Judge Arpert:

Pursuant to your June 5, 2025 email requesting a joint status report, the parties respectfully submit this statement concerning the status of expert disclosures. The parties would appreciate Your Honor's guidance on the schedule for the balance of discovery.

Relator's Statement

Relator prefers a brief telephone or video status conference with Your Honor at your earliest convenience. To facilitate an efficient discussion, Relator offers a brief summary of recent developments and a proposed schedule below.

In April, Defendants deposed Relator's seven experts. On April 26, Defendants served four expert rebuttal reports. Upon Defendants' motion, Your Honor granted Defendants an additional extension of time to serve remaining reports on or before May 7. Defendants served four additional expert reports on May 8.

Relator served on June 4, 2025 deposition notices for Defendants' rebuttal experts. Those depositions are noticed for August 6 through August 22, 2025. Defendants say that they are conferring with their experts concerning their availability on the noticed dates, and the parties will discuss in good faith any adjustments necessary. Relator proposes that all expert depositions should conclude by August 22, 2025, because Relator intends to serve responsive reports, if any, to Defendants' rebuttal reports by August 29, closing expert discovery.

Relator hopes to avoid any further delays or extensions and therefore requests Your Honor to order that Relator may serve any reply reports by August 29, 2025 (without prejudice to any party's objections to the scope of the reply reports). Expert discovery would therefore close on that date. Thereafter, Relator intends to request the Court to schedule a status conference in early September to set dates for summary judgment and *Daubert* motions to be fully briefed by December 31, 2025, as well as to schedule an initial pretrial conference on or before February 28, 2026. Thus, to summarize, Relator proposes that Your Honor enter an order setting the following dates to close discovery, which will allow the case to proceed expeditiously to the next phase of litigation, during which Relator will ask the Court to set a schedule for briefing of dispositive and *Daubert* motions and for the initial pretrial conference:

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Relator's Depositions of Defendants' Experts Conclude: August 22, 2025

Deadline for Relator to Serve Reply Reports: August 29, 2025

Expert Discovery Ends: August 29, 2025

Relator understands that Defendants dispute whether reply reports are appropriate, because Defendants purportedly served only rebuttal reports, not affirmative ones. This position overlooks the scheduling framework which contemplates that Relator, the party with the burden of proof, would have an opportunity to respond to Defendants' reports, regardless of how Defendants chose to label them. This structure mirrors the approach in the underlying ANDA litigation before this Court that invalidated the same patent at issue here. *See BTG Int'l Ltd. v. Amneal Pharmaceuticals LLC*, Case No. 15-05909 (KM) (JBC) (ECF 335) ("the party with the burden of proof was to make its case in an opening report and then have an opportunity to reply to arguments raised in rebuttal by the opposing party").

Accordingly, the parties in the underlying ANDA litigation served multiple expert reply reports, including Defendants. In fact, Defendants even found it necessary to serve sur-reply expert reports, *see* No. 2:15-cv-05909-KM-ESK, at ECF 335. And as Defendants note, *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd.*, No. 22-1232 (JXN) (JSA), 2024 WL 5202484 (D.N.J. Dec. 19, 2024), adopting Report and Recommendation, 2024 WL 5203037, similarly permitted reply reports. There is no reason to depart from past practice in this case, particularly given the complexity and importance of the issues at stake—which, for example, required Defendants to take ten months to serve eight expert rebuttal reports. It makes no sense to deprive Relator of the ability to respond at all, based on Defendants' attempt to fashion their reports as "rebuttals."

Relator believes the same structure for expert reports employed in the underlying ANDA litigation, and in *Mylan*, for example, is embodied by the existing schedule here. The prior schedules contemplated that Relator would serve opening reports, Defendants would serve "expert report(s) and rebuttal(s)," and then Relator would subsequently serve "rebuttal expert report(s)." (ECF 335) Relator never understood that Defendants could unilaterally deprive Relator—who has the burden of proof—of the opportunity to respond to Defendants' experts by simply naming their expert reports "rebuttal" reports.¹ Indeed, many of Defendants' expert reports are essentially affirmative reports that repeatedly go far beyond the scope of the reports to which they are purportedly "rebutting."²

¹ Defendants say below that they believe the "cadence" of the prior scheduling orders counsels against the submission of reply reports by Relator. Defendants' reliance on the contemplated "cadence" of expert discovery is ironic, because it was Defendants who caused an extended pause in the original cadence and tempo—by asserting multiple pretextual reasons to extend the time for them to serve their expert reports from four months to ten.

² Relator objects to the scope of Defendants' reply reports and reserves the right to assert his objections at the appropriate time.

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Moreover, Fed. R. Civ. P. 26(a)(2)(D)(ii) generally permits the service of an expert report that is “intended solely to contradict or rebut” an expert opinion “on the same subject matter identified by another party”; *see also Crowley v. Chait*, 322 F. Supp. 2d 530, 550 (D.N.J. 2004). That describes this situation precisely.³ Indeed, the prior scheduling order clearly provided Relator the opportunity to serve “rebuttal” reports (ECF 335), which are intended to “explain, repel, counteract or disprove the evidence of the adverse party.” *United States v. Chrzanowski*, 502 F.2d 573, 576 (3d Cir. 1974). Given Defendants’ gambit to call all of their expert reports as “rebuttals,” Relator’s proposed reply reports are intended to serve the very purpose contemplated in the foregoing authorities. On the other hand, Defendants’ proposal would impermissibly require “the inclusion of vast amounts of arguably irrelevant material in an expert’s report on the off chance that failing to include any information in anticipation of a particular criticism would forever bar the expert from later introducing the relevant material,” *Crowley*, 322 F. Supp. 2d at 551. The Court should therefore avoid a ruling that would essentially require a party in Relator’s position to anticipate and include in an affirmative report a prospective rebuttal of any possible argument that could be raised by Defendants or be excluded. *Cf. Hill v. Reederei F. Laeisz G.M.B.H., Rostock*, 435 F.3d 404, 423 (3d Cir. 2006) (there is no requirement that “every opinion by an expert must be preliminarily stated in the report, or forever be precluded.”).

Given the complexity of the issues, and the importance of expert opinions for this case, Your Honor should resolve any ambiguity over the intent of the prior scheduling orders to avoid prejudice to Relator, and to further basic fairness in permitting Relator a chance to have at least one opportunity to respond to Defendants’ experts. Indeed, Defendants do not make any

³ Defendants incorrectly imply that Relator “belatedly” insisted—only after “exchanging multiple iterations of a draft letter”—that his proposed reply reports are intended to address new subject matter raised for the first time by Defendants. That misrepresents Relator’s consistent position that he is entitled to respond generally to Defendants’ expert reports under Fed. R. Civ. P. 26(a)(2)(D)(ii). The fact that Defendants *also* introduces many new issues in their supposed “rebuttal” provide further justification for Relator’s proposed reply reports.

Defendants’ characterization of Relator’s position as “belated” is also incorrect. Relator proposed that the parties provide Your Honor with a proposed schedule on June 4. Following Your Honor’s request for a status report on June 5, Relator wrote to Defendants on June 6 with a proposed joint status letter. Defendants delayed their preliminary objection to Relator’s proposed schedule until June 10—and they did not elucidate their argument (to which Relator was responding) until June 11. Relator’s point—that Defendants say is “belated”—was conveyed to them on June 12, reflecting a timely response.

Finally, Defendants erroneously suggest that Relator has previously “pivoted” to new theories, citing Your Honor’s order at ECF 374 (denying Relator’s motion for *in camera* review). Relator respectfully clarified that the supposed “new theory”—Defendants’ improper listing of the fraudulent patent in the Orange Book—was an integral part of Defendants’ fraudulent scheme and was specifically alleged in the SAC, *see* ECF 394, at 25-26, *citing* SAC, ECF 63, at ¶¶ 40-42, 48-51, 58, 92, 96-98, 119. The Court subsequently granted Relator’s requested relief for *in camera* review, *see* ECF 417, and on April 2 requested Defendants to provide the priority documents identified by Relator so it could review them; the parties await the Court’s decision.

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substantive arguments that affording Relator a chance to respond would be prejudicial to them, or otherwise improper on its merits.

Relator therefore believes that the most efficient route is for any motions that object to the propriety of Defendants' reports or Relator's reply reports to be made by a motion to exclude or *Daubert* motion after expert discovery closes, along with all the other issues directed to the admissibility of the parties' respective expert reports and proffered opinions. This avoids two separate rounds of motions directed to expert reports. Relator's proposal also permits such motions to be briefed and decided with the benefit of the specific reports being challenged. In contrast, Defendants' proposal appears simply to be advocating for additional delay through another round of briefing—which would likely have to take place much closer to the end of expert discovery, after Relator has substantially finished drafting the replies. This would also deprive the Court of the benefit of seeing the actual reports themselves in determining whether they fairly answer new matter raised by Defendants in “rebuttal,” as opposed to on an “affirmative” report. That proposal represents the worst of both worlds. The Court should simply cut through all of this and decide now to afford Relator the opportunity to respond at least once to Defendants' experts—which Relator intends to accomplish in less than half the time Defendants took—without prejudice to Defendants' right to move to exclude any reply opinions they believe exceed the scope of the rebuttal opinions to which they respond.

Defendants also say they may be entitled to a second round of expert depositions if Relator serves a reply report. Relator submits that such depositions are unwarranted under the “good cause” standard set forth in *Mylan*, 2024 WL 5202484; *see also* Order, ECF 431 (noting that *Mylan* is “instructive”). Defendants knew the limitations on the circumstances in which second depositions of experts are permitted, but nevertheless insisted on taking the depositions of Relator's experts prior to Defendants serving their reports. Regardless, any motion by Defendants to take additional depositions should be made only after reply reports are actually served, *see id.* Relator proposes that any such a motion may be made, if necessary, within two (2) weeks after service of the relevant reply report, notwithstanding the expert discovery deadline.

Finally, Relator wishes to reiterate that the parties have agreed to table their dispute concerning Relator's Requests for Admission Nos. 21-25 (requesting Defendants to admit that certain documents produced by them are authentic business records and admissible) until the parties meet and confer about stipulations for the admissibility of documents prior to trial.⁴

⁴ Relator has requested Defendants to withdraw their “Outside Counsels’ Eyes Only” confidentiality designation of certain documents so that he can review them to prepare for trial. Defendants also finally produced last week a 30(b)(6) corporate representative to testify on the topics that Your Honor ordered nearly a year ago. Relator believes the witness dodged many questions through a lack of preparation, and Relator is currently seeking to resolve these issues informally with Defendants to avoid further burdening Your Honor with additional motion practice, while reserving all rights.

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Defendants' Statement

Defendants agree that a status conference would be appropriate to resolve the open issues discussed below and can make themselves available at the Court's convenience. Because of the nature and importance of the issues presented, Defendants submit that an in-person status conference would be appropriate to resolve these disputes. Defendants address other points raised by Relator's statement below.

Defendants' Expert Reports / Expert Depositions

On April 26, 2025, Defendants served four rebuttal expert reports. The Court further granted Defendants an extension until May 7, 2025, to serve additional rebuttal expert reports based on the unavailability of one of Relator's expert witnesses until after Defendants' expert report deadline. Defendants served three additional rebuttal expert reports at 12:10 AM Eastern on May 8, 2025. Defendants served a fourth rebuttal expert report four minutes later, at 12:14 AM Eastern. As Defendants explained in an email to counsel to Relator serving those reports, the de minimis delay resulted from a technical issue in finalizing one of the reports. Relator has not objected to that inconsequential delay.

Defendants have also completed their depositions of Relator's experts based on those experts' affirmative reports. The parties are currently scheduling depositions of Defendants' experts based on those experts' rebuttal reports.

Relator's Request to Amend the Scheduling Order

Defendants object to Relator's request to modify the expert discovery schedule. Although Relator frames his request as one to modify the current expert discovery deadlines, his request actually contemplates that the Court amend the scheduling order to permit him to file an entirely new category of expert reports. Relator offers no justification for his filing of those reports and his request is improper. If Relator wishes to serve reply expert reports, the appropriate path is for Relator to seek leave from the Court explaining why, on a report-by-report basis, he is entitled to a reply report.

The discovery schedule has been in place for three years. On May 25, 2022, Judge Kiel entered a scheduling order based on a vigorously negotiated proposal by the Parties. ECF 213. That schedule called for Relator to serve his affirmative expert reports first, followed by any affirmative reports and/or rebuttals from Defendants, with any of Relator's rebuttals to Defendants' affirmative reports following Defendants' reports. *Id.* at 2-3. That cadence makes plain that reply reports were not contemplated; if they had been, the order would have provided for further reports from Defendants in response to Relator's rebuttals (i.e., reply reports).

The Court has modified the scheduling *deadlines* multiple times since May 2022. Yet the *structure and cadence* of the schedule has remained unchanged, including that the Parties are

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entitled only to affirmative reports and rebuttals to affirmative reports.⁵ *See* ECF 421. It is only now—after three years of discovery, after Defendants deposed Relator’s experts, and after Defendants served extensive expert rebuttals—that Relator asks the Court to amend the schedule to permit replies. The Court should not do so.

Relator is also wrong that failing to amend the scheduling order would “deprive” him of the opportunity to file responsive reports. That argument relies on the mistaken premise that the Federal Rules entitle Relator to replies because he has the burden of proof. They do not. Instead, the Rules provide for the disclosure of expert opinions, Fed. R. Civ. P. 26(a)(2)(B), and opinions “to contradict or rebut evidence on the same subject matter identified by another party under Rule 26(a)(2)(B),” *id.* 26(a)(2)(d)—i.e., rebuttals. The scheduling order negotiated here reflects the language of those rules; it provides for “expert reports” and “rebuttals,” but not the replies Relator insists he is entitled to. And it is entirely ordinary that Relator, as the party with the burden of proof, must make his disclosures first without the opportunity to reply to Defendants’ disclosures. *See* 1993 Notes to Fed. R. Civ. P. 26, Paragraph (2) (“[I]n most cases the party with the burden of proof on an issue should disclose its expert testimony on that issue before other parties are required to make their disclosures with respect to that issue.”). Indeed, that is the structure reflected in this Court’s standard discovery plan, which provides for the plaintiff’s expert reports before the defendant’s (and says nothing about replies). Joint Proposed Discovery Plan (Template), https://www.njd.uscourts.gov/sites/njd/files/forms/R16DiscoveryPlan_1.pdf.

After exchanging multiple iterations of a draft letter, Relator belatedly insists that his reports actually are rebuttals insofar as they rebut *new subject matters* raised for the first time in Defendants’ reports and not previously addressed by one of Relator’s experts. *See* Fed. R. Civ. P. 26(2)(C)(D)(ii). Defendants submit that none of their experts have raised such new subject matter, and Relator has offered no example—to the Court or Defendants—demonstrating otherwise. If Relator believes that any such reports do so, he should face no difficulty identifying those aspects of the reports here. Of course, Relator’s rebuttal reports would be limited only to addressing that *new* subject matter identified in Defendants’ reports; they are “not an opportunity for the correction of any oversights in [his] case in chief.” *Crowley v. Chait*, 322 F. Supp. 2d 530, 551 (D.N.J. 2005). But as Relator’s arguments and inconsistent description of the reports⁶ suggest that is how he intends to leverage his reply reports. Indeed, it has been Relator’s practice throughout the litigation to pivot to entirely new theories of liability after his initial case falls flat. *See* Special Master Order

⁵ Defendants identified this issue for the Court in January when they moved for an order compelling Relator to provide his experts for depositions. ECF 425 at 5-6. But Relator did not assert a right to reply reports in response to that motion; instead, Relator asserted only that depositions of Relator’s experts should wait until Relator served “rebuttal reports.” ECF 429 (“[I]f Defendants insist on taking depositions prior to serving their initial reports, they are knowingly foregoing the right to take their depositions again after the experts provide their *rebuttal* opinions.”).

⁶ Relator at various times describes his reports as “replies,” “responsive,” and “rebuttal,” each of which has a distinct meaning. But the scheduling order uses only one of those terms—“rebuttal.”

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Denying Relator's Motion for *In Camera* Review, ECF 374 (rejecting "theories [that] fall outside the claims set forth in Relator's pleading"). That is not the purpose of a rebuttal report.

Relator fails to point to any other authority supporting his atextual interpretation of the scheduling order in this case. Relator points to the scheduling order from the ANDA litigation as evidence of the appropriate procedure to follow here. But that is a different scheduling order, in a different case, negotiated by different parties. And, troublingly for Relator, the parties in the ANDA litigation *specifically* negotiated a schedule that included "reply reports."⁷ ECF 164 at 5, 15-cv-05909-KM-JBC (D.N.J. Feb. 4, 2016). The other case cited by Relator has the same flaw—the negotiated schedule *explicitly* called for replies.⁸ See *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd.*, 2024 WL 5203037, at *2 (D.N.J. Nov. 25, 2024) (report and recommendation), *adopted by* 2024 WL 5202484 (Dec. 19, 2024). Again, that is not the schedule in this case.

The Court should also reject Relator's unworkable proposal to resolve this dispute. Relator insists that Defendants should litigate the propriety of his reply reports only *after* he serves those impermissible reports. But that improperly would shift Relator's burden to Defendants. See *Faiella v. Sunbelt Rentals, Inc.*, 341 F.R.D. 553, 561 (D.N.J. 2022) (recognizing the party serving discovery outside the scope of the scheduling order bears the burden of establishing that discovery is permissible); *Lee v. Kmart Corp.*, 2016 WL 4373694, at *1 (D.V.I. Aug. 15, 2016) (rejecting argument that opposing party bears the burden of striking a party's willful noncompliance with a scheduling order). Under Relator's proposal, these reports would be treated as presumptively permissible, and Defendants would be tasked with moving to exclude them. Given Relator's other scheduling proposals, those efforts would occur simultaneous to Defendants' briefing on important dispositive issues, including *Daubert* motions and motions for summary judgment.

That is fundamentally unfair to Defendants. Relator's reply reports will likely impact the scope of Defendants' *Daubert* and summary judgment motions. Thus, if this dispute is not resolved now, Defendants will face the prospect of briefing dispositive motions with the

⁷ Relator also bizarrely points to a motion for leave to file a sur-reply expert report filed by Defendants in the ANDA litigation to support his argument. ECF 335, 15-cv-05909-KM-JBC (D.N.J. July 12, 2017). But that motion just proves Defendants' point. The party seeking to file a report not permitted by the scheduling order should seek leave to do so and specifically explain why the additional report should be permitted; the burden should not fall on the other party to strike that report. That is what Defendants have proposed Relator do here.

⁸ As Judge Hochberg's report and recommendation notes, the scheduling order in *Mylan* provided for the following:

"Parties shall serve expert report(s) on merits issues on which they bear the burden of proof on November 21, 2025....

Parties shall serve responsive merits expert reports on January 30, 2026....

The Parties shall serve replies on merits expert reports on March 13, 2026."

2024 WL 5203037, at *2. This language thus demonstrates that the scheduling order in the present case does not permit reply reports.

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uncertainty of whether Relator can even rely on his improper reply reports. And any dispute over Relator's reply reports would likely remain open as those dispositive issues are briefed. The Court should reject such an approach.

The more sensible path is to resolve the issue now. If Relator would like to file a reply or supplemental report, he should make a motion to the Court for leave to do so and explain why he believes he is entitled to such a report. Defendants could then file an opposition, and the Court can resolve that dispute well in advance of *Daubert* and summary judgment briefing. This is also the more efficient approach. Relator wrongly indicates that the resolution of the dispute turns on the specific nature of each reply. It does not. The two questions before the Court are (1) whether the scheduling order permits reply expert reports (it does not), and (2) if not, whether Relator should be permitted to file such reports. Those questions turn on the content of the scheduling order, and the expert reports that have already been filed; they do not turn on the specific contents of Relator's reply reports. The Court should resolve the question now.

Moreover, if the schedule is amended to permit reply reports (or if Relator is permitted reply reports on a case-by-case basis), Defendants should be permitted to depose any expert serving such a report. Again, Relator is wrong that Defendants must bear the burden of justifying such a deposition after he serves such a report. Defendants were permitted to rely on the relative certainty provided by the scheduling order. Indeed, Defendants' litigation strategy specifically accounted for the reports permitted by the scheduling order. Relator offers no argument, and points to no authority, supporting his position that Defendants were required to take into consideration impermissible expert reports when they noticed depositions.

The Court should reject Relator's proposal.

Other Pre-Trial Scheduling

Relator also requests that, after the close of expert discovery, the Court enter a schedule for briefing on other remaining pre-trial issues, including *Daubert* motions and motions for summary judgment. Defendants agree that the Court should enter a pre-trial schedule for *Daubert* briefing and motions for summary judgment. But Defendants disagree with the other aspects of Relator's proposal.

Relator's proposal to set a schedule in September, which would provide for *Daubert* motions and motions for summary judgment to be fully briefed by December 31, 2025, again disregards the schedule that the Parties previously agreed upon. That schedule contemplated that the Parties brief *Daubert* motions first, with motions for summary judgment to follow. *See* ECF 217, 270. That cadence would permit the Court to resolve *Daubert* challenges that might shape the parties' summary judgment motions. Relator's schedule disregards this, and provides for simultaneous *Daubert* and summary judgment briefing on a more compressed schedule than that previously agreed upon. And he proposes doing so over the holiday season. Moreover, Relator's proposed schedule fails to allot any time for Defendants to conduct depositions based on Relator's reply expert reports. Relator instead asks that the Court *eliminate* a month from the previously agreed and ordered expert discovery period, advancing the close of expert discovery from September 29 to August 29. As discussed above, Defendants are entitled to conduct such

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depositions and any schedule must permit time for those depositions to take place. If anything, reply reports would necessitate an extension of that deadline.

In contrast to that proposal, Defendants suggest that each party submit a proposed pre-trial schedule to the Court for its review, after which the Court will enter an order setting a schedule going forward.

Other Issues

Relator's statement also identifies several other purported issues for the Court, including potential disputes regarding fact depositions, confidentiality designations, and Requests for Admission. As Relator's statement makes clear, none of these issues are ripe for the Court—indeed, many have not even been raised with Defendants outside of Relator providing revisions to this submission. The Court should disregard them as unripe.

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Respectfully yours,

SILLS CUMMIS & GROSS P.C.

By: Jeffrey J. Greenbaum

JEFFREY J. GREENBAUM

jgreenbaum@sillscummis.com

GREGORY E. REID

greid@sillscummis.com

One Riverfront Plaza

Newark, New Jersey 07102

Phone: (973) 643-7000

Facsimile: (973) 643-6500

SIDLEY AUSTIN LLP

GORDON D. TODD (*pro hac vice*)

gtodd@sidley.com

BRIAN P. MORRISSEY (*pro hac vice*)

bmorris@sidley.com

LAUREN KATZEFF (*pro hac vice*)

lkatzeff@sidley.com

ALARIC R. SMITH (*pro hac vice*)

alaric.smith@sidley.com

1501 K Street, N.W.

Washington, DC 20005

Telephone: (202) 736-8000

*Attorneys for Defendants Janssen
Biotech, Inc., Janssen Oncology, Inc.,
Janssen Research & Development, LLC,
and Johnson & Johnson*

**LITE DEPALMA GREENBERG & AFANADOR,
LLC**

By: Bruce D. Greenberg

BRUCE D. GREENBERG

570 Broad St, Suite 1201

Newark, NJ 07102

Tel: (973) 623-3000

bgreenberg@litedepalma.com

HERRERA KENNEDY LLP

NICOMEDES SY HERRERA (*pro hac vice*)

BRET D. HEMBD (*pro hac vice*)

1300 Clay Street, Suite 600

Oakland, California 94612

Telephone: (510) 422-4700

NHerrera@HerreraKennedy.com

BHembd@HerreraKennedy.com

SPARACINO PLLC

TEJINDER SINGH (*pro hac vice*)

1920 L Street, NW, Suite 835

Washington, DC 20036

Telephone: (202) 629-3530

TSingh@sparacinopllc.com

MORGAN & MORGAN

JAMES YOUNG (*pro hac vice*)

501 Riverside Ave, Suite 1200

Jacksonville, FL 32202

Telephone: (904) 361-0012

JYoung@ForThePeople.com

MORGAN & MORGAN

CLARK BOLTON (*pro hac vice*)

JUAN MARTINEZ (*pro hac vice*)

201 N Franklin Street, 7th Floor

Tampa, FL 33602

Telephone: (813) 223-5505

CBolton@ForThePeople.com

JuanMartinez@ForThePeople.com

*Attorneys for Plaintiff-Relator
Zachary Silbersher*